DEC 17 2010

**TO:** Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

**FROM:** George M. Reeb
Acting Deputy Inspector General for Audit Services

**SUBJECT:** Review of the Centers for Disease Control and Prevention's (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) With Select Agent Regulations (A-04-08-01056)

The attached final report provides the results of our review of the Centers for Disease Control and Prevention's (b)(3) 42 USC 262a(h) compliance with select agent regulations. This review is one of six reviews of Federal (b)(3) 42 USC 262a(h) compliance with select agent regulations.

This report contains restricted, sensitive information that may be exempt from release under the Freedom of Information Act, 5 U.S.C. § 552. The report will not be posted on the Internet. If information in the report is released pursuant to a request under the Act, the restricted, sensitive information and other information exempt from release will be redacted.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. We look forward to receiving your final management decision within 6 months. Please refer to report number A-04-08-01056 in all correspondence.

Attachment

Department of Health & Human Services

**OFFICE OF INSPECTOR GENERAL**

# REVIEW OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S (b)(3) 42 USC 262a(n) (b)(3) 42 USC 262a(n) COMPLIANCE WITH SELECT AGENT REGULATIONS

[redacted]


Daniel R. Levinson
Inspector General

December 2010
A-04-08-01056

# *Office of Inspector General*

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health & Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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## OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

# EXECUTIVE SUMMARY

## BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. § 262a, requires the Department of Health & Human Services (HHS) to regulate select agents, which are biological materials that have the potential to pose a severe threat to public health and safety. Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture, CDC establishes select agent regulations and monitors and enforces compliance with the regulations.

Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that possesses, uses, or transfers select agents must register with CDC and comply with Federal select agent regulations. (We refer collectively to these organizations as "entities.") Entities must, among other things, appoint a Responsible Official to ensure compliance with the regulations; restrict access to select agents to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"); develop and implement security, biosafety, and incident response plans; provide training on biosafety and security; maintain detailed select agent inventory and access records; and comply with select agent transfer requirements.

Following the 2001 terrorist attacks and anthrax release, we conducted a series of reviews of compliance with Federal select agent regulations by State, local, nonprofit, and university laboratories. In April 2008, we began a series of similar reviews at six Federal entities. This review, one in the series, addresses compliance by CDC's (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h)

## OBJECTIVE

Our objective was to determine whether 42 USC 262 complied with Federal select agent regulations.

## SUMMARY OF FINDINGS

42 USC 262 complied with some Federal select agent regulations. Specifically, 42 USC 262 had appointed a Responsible Official and developed and implemented an incident response plan. However, 42 USC 262 did not always:

- ensure the physical security of select agents or restrict access to select agents to approved individuals,
- ensure that individuals received select agent training,

- maintain required inventory records or ensure that select agent inventory was stored only in registered areas, or

- obtain DSAT approval to transfer select agents or ensure that only approved individuals accepted delivery of select agents.

These weaknesses could have compromised 3) 42 USC 262a ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who work with select agents.

## RECOMMENDATIONS

We recommend that 3) 42 USC 262a

- follow its security plan requirements regarding physical security measures,

- ensure that only approved individuals are allowed access to select agent areas,

- ensure that all required training is provided to approved individuals,

- ensure that inventory records describe the precise location of all select agents and that select agents are stored only in areas listed on the certificate of registration, and

- include in its biosafety plan a requirement to confirm that materials are inactive before transferring them without authorization.

## CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In comments on our draft report, CDC concurred in principle with our recommendations and provided detailed information on its current and planned security measures. CDC did not concur with some of our findings. CDC also submitted technical comments, which we addressed as appropriate. The complete text of CDC's comments is included as Appendix B.

In response to CDC's comments, we revised three findings and one recommendation.

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**APPENDIXES**

# INTRODUCTION

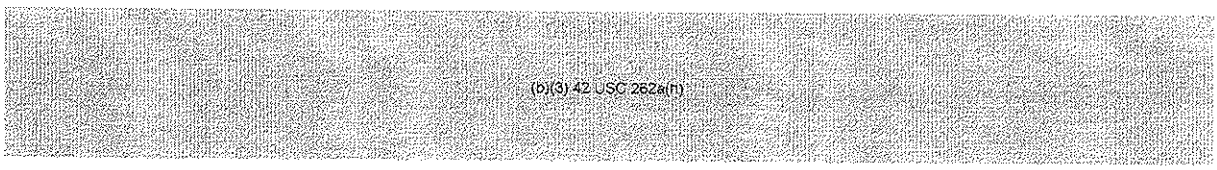
## BACKGROUND

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 42 U.S.C. § 262a, requires the Department of Health & Human Services (HHS) to regulate select agents, which are biological materials that have the potential to pose a severe threat to public health and safety.[1] Within HHS, this responsibility has been assigned to the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT). In collaboration with the U.S. Department of Agriculture (USDA), CDC establishes select agent regulations and monitors and enforces compliance with the regulations.[2]

Any government agency (Federal, State, or local), academic institution, research organization, or other legal entity that possesses, uses, or transfers select agents must register with CDC and comply with Federal select agent regulations. (We refer collectively to these organizations as "entities.")

### Federal Select Agent Regulations

Federal select agent regulations (42 CFR part 73) require that entities, among other things, appoint a Responsible Official to ensure compliance with the regulations; restrict access to select agents to individuals approved by the HHS Secretary based on a security risk assessment by the Attorney General (referred to as "approved individuals"); develop and implement security, biosafety, and incident response plans; provide training on biosafety and security; maintain detailed select agent inventory and access records; and comply with select agent transfer requirements. Appendix A contains the specific Federal regulations relevant to this review.




[1] For purposes of this report, "select agents" refers to all agents and toxins listed in 42 CFR §§ 73.3 and 73.4.

[2] CDC regulates select agents that could pose a severe threat to public health and safety. USDA's Animal and Plant Health Inspection Service (APHIS) regulates select agents and toxins that could pose a severe threat to animal or plant health. CDC and APHIS coordinate regulatory activities for those agents that affect both humans and animals (known as overlap select agents and toxins).

(b)(3) 42 USC 262a(h)

### Office of Inspector General Reviews

Following the 2001 terrorist attacks and anthrax release, we conducted a series of reviews of compliance with Federal select agent regulations by State, local, nonprofit, and university laboratories. In April 2008, we began a series of similar reviews at six Federal entities. This review is one in the series.

In addition, in a prior review, we determined whether only approved individuals accessed select agents transferred to and from (b)(3) 42 USC 262a(h)

(b)(3) 42 USC 262a(h)

## OBJECTIVE, SCOPE, AND METHODOLOGY

### Objective

Our objective was to determine whether (b)(3) 42 USC 262 complied with Federal select agent regulations.

### Scope

Our review covered the period April 18, 2005, the effective date of HHS's final rule for implementing select agent regulations,[5] through April 2009. We did not perform an indepth review of (b)(3) 42 USC 262a internal control structure. Rather, we limited our review to controls related to (b)(3) 42 USC 262a compliance with select agent regulations.

We performed our fieldwork at (b)(3) 42 USC 262a(h)

(b)(3) 42 USC 262a(h)

[5] 70 Fed. Reg. 13294–13325 (Mar. 18, 2005).

## Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed CDC records related to 3) 42 USC 262a registration;
- reviewed 3) 42 USC 262a select agent security plan, biosafety plan, and incident response plan;
- held discussions with ) 42 USC 262 and DSAT officials to gain an understanding of policies and procedures for implementing select agent regulations;
- tested 3) 42 USC 262a security, biosafety, and incident response procedures;
- reviewed 3) 42 USC 262a records related to biosafety and security training provided to a judgmentally selected sample of 30 approved individuals;
- reviewed (3) 42 USC 262a select agent inventory and access records; and
- reviewed 3) 42 USC 262a procedures for transferring select agents.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

## FINDINGS AND RECOMMENDATIONS

) 42 USC 262 complied with some Federal select agent regulations. Specifically, ) 42 USC 262 had appointed a Responsible Official and developed and implemented an incident response plan. However, ) 42 USC 262 did not always:

- ensure the physical security of select agents or restrict access to select agents to approved individuals,
- ensure that individuals received select agent training,
- maintain required inventory records or ensure that select agent inventory was stored only in registered areas, or

- obtain DSAT approval to transfer select agents or ensure that only approved individuals accepted delivery of select agents.

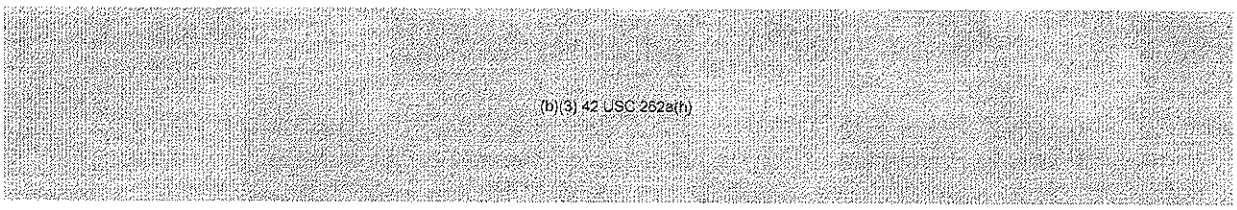
These weaknesses could have compromised (b)(3) 42 USC 262a ability to safeguard select agents from accidental or intentional loss and to ensure the safety of individuals who work with select agents.

## SELECT AGENT ACCESS

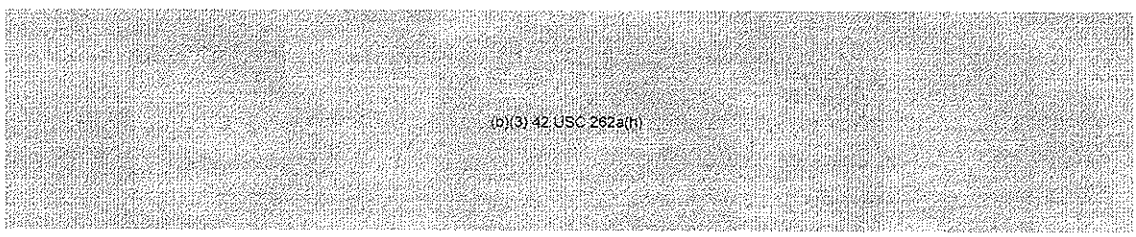
Pursuant to 42 CFR § 73.11(a), entities must develop and implement a written security plan to safeguard select agents against unauthorized access, theft, loss, or release. Further, 42 CFR § 73.11(c)(5) states: "The security plan must ... [d]escribe ... protocols for changing access numbers or locks following staff changes ...."

Pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to approved individuals.[6] In addition, 42 CFR § 73.10(j) states that the Responsible Official must immediately notify CDC when an individual's access to select agents is terminated and the reasons for the termination.

### Physical Security of Select Agents




(b)(3) 42 USC 262 did not fully adhere to its security plan requirements. Specifically:

- 

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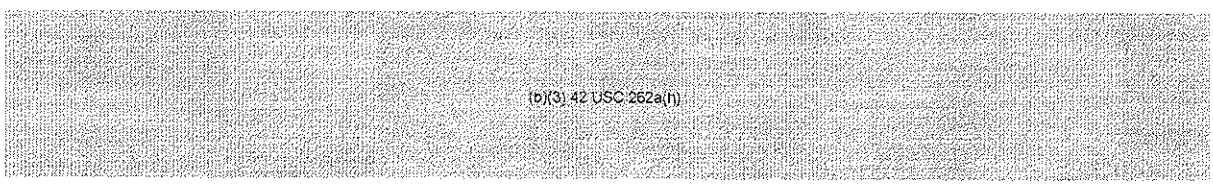
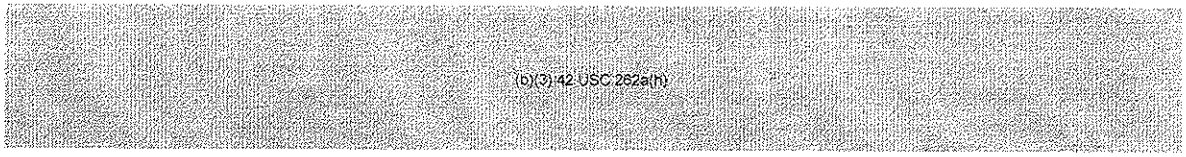
[6] Pursuant to 42 CFR § 73.11(d)(2), an entity may allow an unapproved individual to conduct routine cleaning, maintenance, repairs, or other activities not related to select agents if the individual is continuously escorted by an approved individual.






### Approved Individuals

According to (b)(3) 42 USC 262a security plan, individuals awaiting notification of approval by the HHS Secretary were allowed to access select agent laboratory and storage areas only if escorted by an approved individual. (b)(3) 42 USC 262a(h)


## SELECT AGENT TRAINING

Pursuant to 42 CFR § 73.15(a), entities must provide biosafety and security training to individuals before they access select agent areas. In addition, 42 CFR § 73.15(b) states that entities must provide annual refresher training to approved individuals.

We could not verify that 10 of 30 sampled approved individuals had received the required training. For three individuals, there was no documentation that they had received any training. For seven individuals, there was no documentation that they had received annual refresher training.

## SELECT AGENT INVENTORY

Pursuant to 42 CFR § 73.17(a)(1), entities must maintain an accurate, current inventory, which includes information showing where each select agent is stored (e.g., building, room, and freezer). In addition, pursuant to 42 CFR § 73.7(g), entities must have a valid certificate of registration for one physical location (a building, a room, or a group of buildings) for select agents.

### Incomplete Inventory Records

Not all select agent inventory records at 42 USC 262 contained the building number, room number, freezer number, or other information required by regulations. (b)(3) 42 USC 262a security plan did not require that these records fully describe the precise storage location of the select agents. The plan stated: "The inventory record does not need to fully describe the location; for example, the rack/box/vial number may be specified explicitly, but the building/floor/room/freezer information may be the same for all, understood by the accountable scientist, and omitted from the record." After our fieldwork, 42 USC 262 officials advised us that 42 USC 262 had revised its security plan to require that inventory records fully describe the storage location of select agents.

### Agents Stored in Areas Not Listed in (b)(3) 42 USC 262a( Registration

(b)(3) 42 USC 262 stored some select agents in areas not listed in its registration. (b)(3) 42 USC 262a(h)

(b)(3) 42 USC 262a(h)

(b)(3) 42 USC 262a(h)

## SELECT AGENT TRANSFERS

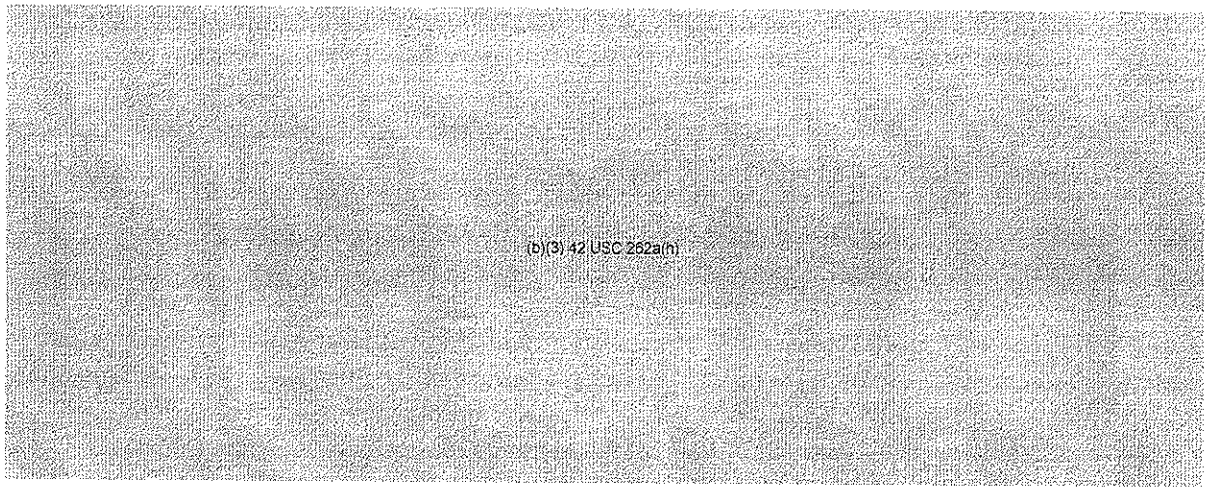
Pursuant to 42 CFR § 73.7(a), "[u]nless exempted under § 73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under § 73.6 or 9 CFR part 121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and Administrator [of APHIS]." Furthermore, 42 CFR § 73.16(a) states: "... a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer." Additionally, pursuant to 42 CFR § 73.10(a), entities may authorize access to select agents only to approved individuals.

### Unauthorized Transfers

On two occasions in 2006, (b)(3) 42 USC 262a(h) without authorization to do so.[12] In late March 2006, (b)(3) 42 USC 262a(h)

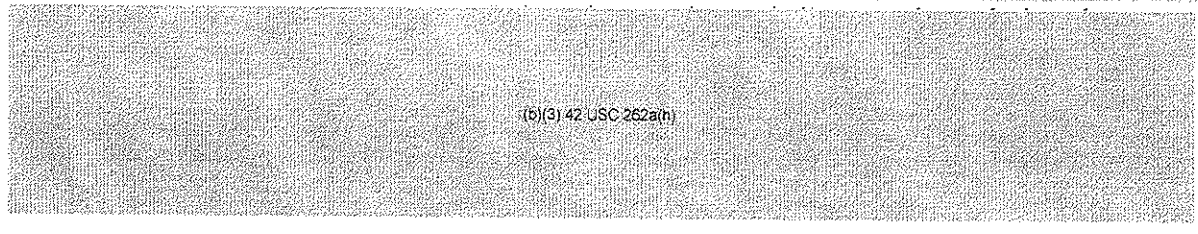
(b)(3) 42 USC 262a(h)

(b)(3) 42 USC 262a(h)




### Packages Received by Unapproved Individuals

During our audit period, six unapproved individuals—five individuals from (b)(3) 42 USC 262a delivery contractor and one security guard—received and signed for packages containing select agents transferred to (b)(3) 42 USC 262a(h)




## RECOMMENDATIONS

We recommend that (b)(3) 42 USC 262a

- follow its security plan requirements regarding physical security measures,
- ensure that only approved individuals are allowed access to select agent areas,
- ensure that all required training is provided to approved individuals,

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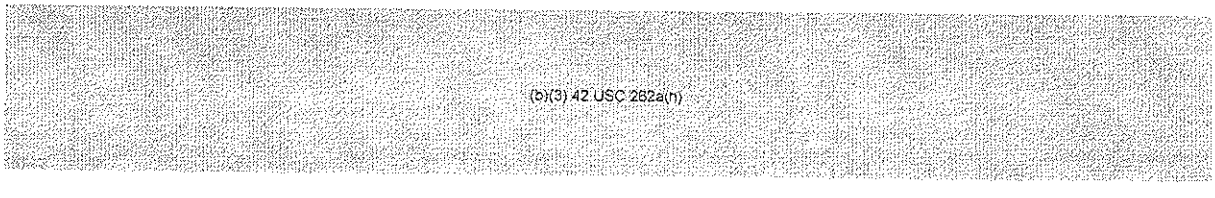


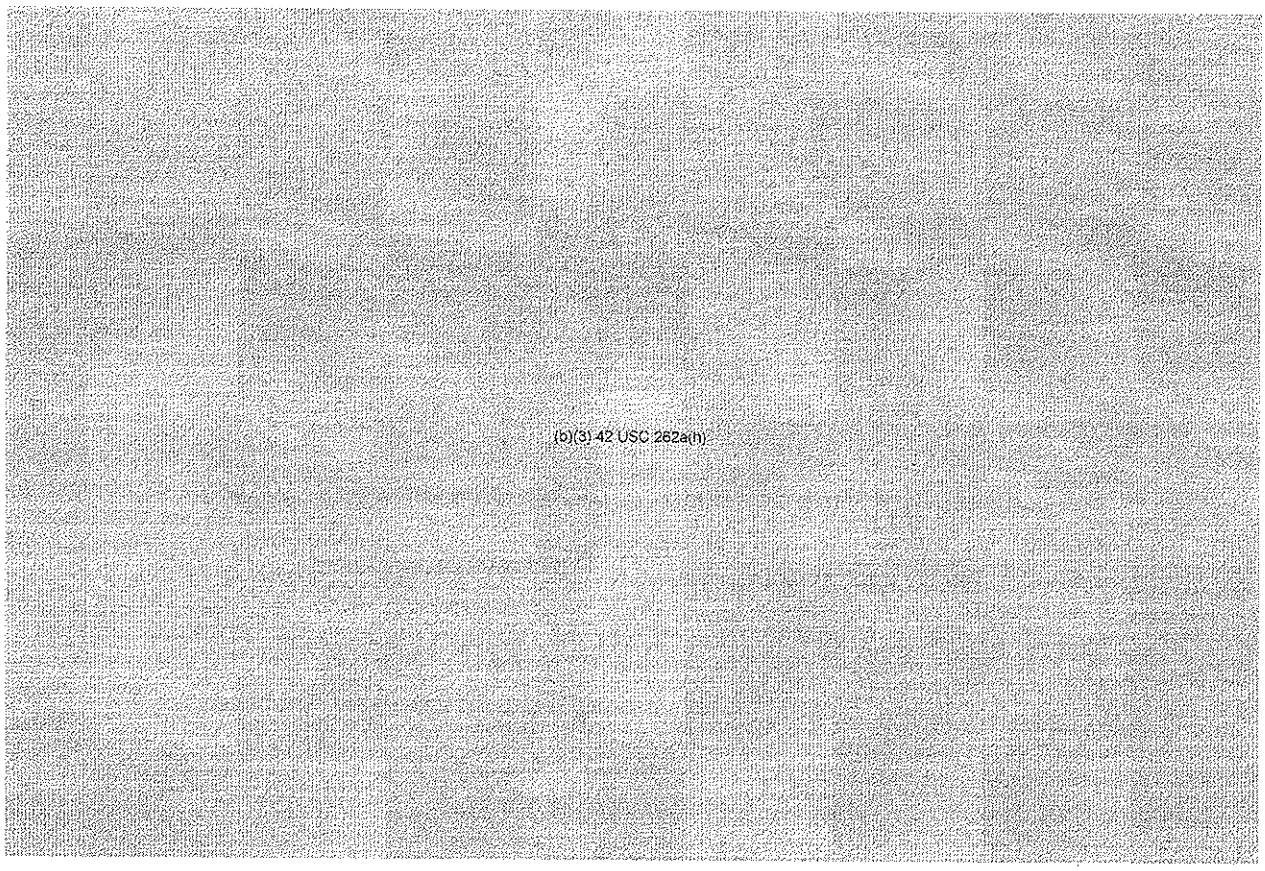
- ensure that inventory records describe the precise location of all select agents and that select agents are stored only in areas listed on the certificate of registration, and

- include in its biosafety plan a requirement to confirm that materials are inactive before transferring them without authorization.

## CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In comments on our draft report, CDC concurred in principle with our recommendations and provided detailed information on its current and planned security measures. CDC did not concur with some of our findings. CDC's comments on those findings and our responses are summarized below. CDC also submitted technical comments, which we addressed as appropriate. The complete text of CDC's comments is included as Appendix B.

In response to CDC's comments, we revised three findings and one recommendation.



# APPENDIXES

## APPENDIX A: FEDERAL SELECT AGENT REGULATIONS

- Regulations (42 CFR §§ 73.3 and 73.4) list select agents and toxins, which are biological materials that have the potential to pose a severe threat to public health and safety (referred to as "select agents" for purposes of the report and this Appendix).

- Regulations (42 CFR § 73.7(a)) require that an individual or entity not possess, use, or transfer select agents without a certificate of registration issued by the Secretary of the U.S. Department of Health & Human Services (HHS).

- Regulations (42 CFR § 73.7(b)) require each entity to designate an individual to be its Responsible Official.

- Regulations (42 CFR § 73.7(g)) require entities to have a valid certificate of registration for one physical location (a building, a room, or a group of buildings) for select agents.

- Regulations (42 CFR § 73.7(h)) require an entity to amend its registration to reflect changes in circumstances (personnel changes, changes in the activities involving any select agent, or the addition or removal of select agents).

- Regulations (42 CFR § 73.9(a)) require that the Responsible Official have the authority and responsibility to act on behalf of the entity and ensure the entity's compliance with requirements of the select agent regulations.

- Regulations (42 CFR § 73.10(a)) require an entity to authorize access to select agents only to individuals approved by the HHS Secretary following a security risk assessment by the Attorney General (referred to as "approved individuals").

- Regulations (42 CFR § 73.10(j)) require the Responsible Official to immediately notify the Centers for Disease Control and Prevention (CDC) (or the U.S. Department of Agriculture) when an individual's access to select agents is terminated and the reasons for the termination.

- Regulations (42 CFR § 73.11(a)) require entities to develop and implement a written security plan. The security plan must be sufficient to safeguard select agents against unauthorized access, theft, loss, or release.

- Regulations (42 CFR § 73.11(b)) require that the entity's security plan be designed according to a site-specific risk assessment and provide protection in accordance with the risk of the select agent, given its intended use.

- Regulations (42 CFR § 73.11(c)) require the entity's security plan to contain procedures for physical security, inventory control, and information systems control, as well as provisions for controlling access to select agents. In addition, each entity's plan must contain provisions for routine cleaning, maintenance, and repairs and procedures for removing

unauthorized or suspicious persons. Each plan must describe procedures for addressing the loss or compromise of keys, passwords, or combinations and protocols for changing access numbers or locks following staff changes. Plans also must contain procedures for reporting unauthorized or suspicious persons or activities; the loss, theft, or release of select agents; or the alteration of inventory records, as well as procedures for ensuring that all approved individuals understand and comply with security procedures.

- Regulations (42 CFR § 73.11(d)) require entities to allow access to select agents only to approved individuals. However, unapproved individuals who conduct routine cleaning, maintenance, repairs, or other activities not related to select agents may access select agent areas only when continuously escorted by an approved individual. In addition, freezers, refrigerators, cabinets, and other containers where select agents are stored are required to be secured against unauthorized access. The security plan also must contain procedures for intraentity transfers of select agents, the avoidance of sharing individuals' unique means of access to select agents, and the separation of select agent areas from public areas.

- Regulations (42 CFR § 73.11(f)) require entities to review annually and revise, as necessary, their security plan. Further, entities must conduct drills or exercises at least annually to test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.12(a)) require entities to develop and implement a written biosafety plan that is commensurate with the risk of the agent, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.

- Regulations (42 CFR § 73.12(d)) require entities to review annually and revise, as necessary, their biosafety plan. Further, entities must conduct drills or exercises at least annually to test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.14(a)) require entities to develop and implement a written incident response plan. The incident response plan must be coordinated with any entitywide plans, kept in the workplace, and available to employees for review.

- Regulations (42 CFR § 73.14(c)) require each entity's incident response plan to contain information related to names and contact information for responsible entity and building officials, personnel roles and lines of authority and communication, planning and coordination with local emergency responders, procedures for employees performing rescue or medical duties, a list of personal protective and emergency equipment, site security and control, procedures for emergency evacuation, and decontamination procedures.

- Regulations (42 CFR § 73.14(d)) require entities to review and revise, as necessary, their incident response plans. Further, entities must conduct drills or exercises at least annually to

test and evaluate the effectiveness of their plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.

- Regulations (42 CFR § 73.15(a)) require entities to provide information and training on biosafety and security to individuals before they access select agent areas.

- Regulations (42 CFR § 73.15(b)) require entities to provide annual refresher training for approved individuals.

- Regulations (42 CFR § 73.15(c)) require entities to maintain a record of training provided to each individual. The record must include the name of the individual, the date of the training, a description of the training, and the means used to verify that the employee understood the training.

- Regulations (42 CFR § 73.16) require entities to transfer a select agent only to an entity registered to possess that particular select agent. Each transfer must be authorized by CDC (or the U.S. Department of Agriculture) before the transfer. In addition, the sender must comply with all laws concerning packaging and shipping.

- Regulations (42 CFR §§ 73.17(a)(1) and 73.17(a)(2)) require entities to maintain complete records relating to select agent inventories.

- Regulations (42 CFR § 73.17(a)(3)) require entities to maintain a current list of all approved individuals.

- Regulations (42 CFR § 73.17(a)(4)) require entities to maintain complete records related to all entries into areas containing select agents, including the name of the individual, name of the escort (if applicable), and date and time of entry.

- Regulations (42 CFR § 73.17(b)) require entities to implement a system to ensure that all records and databases created under 42 CFR part 73 are accurate, that access to them is controlled, and that their authenticity may be verified.

# APPENDIX B: CENTERS FOR DISEASE CONTROL AND PREVENTION COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 23 2010

TO: Daniel R. Levinson
Inspector General
Department of Health and Human Services (HHS)

FROM: Director
Centers for Disease Control and Prevention

SUBJECT: Office of Inspector General's Draft Report: "Review of the Centers for Disease Control and Prevention's (b)(3) 42 USC 262a(h) Compliance With Select Agent Regulations" June 23, 2010 (A-04-08-01056)

The Centers for Disease Control and Prevention (CDC), Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) and the Office of Security and Emergency Preparedness (OSEP) appreciate the opportunity to review and provide comments on the Office of Inspector General's draft report, "Review of the Centers for Disease Control and Prevention's 42 USC 262a (b)(3) 42 USC 262a(b) Compliance with Select Agent Regulations" (A-04-08-01056). Thank you for your review of this important issue.

## OBJECTIVE

As stated in the draft, the objective of this review was to determine whether 42 USC 262 complied with Federal select agent regulations. The draft identified five findings regarding the CDC 42 USC 262 Laboratory's compliance with select agent regulations.

## SUMMARY OF FINDINGS

The draft provided a summary of findings (Page i) that stated that 42 USC 262 complied with some Federal select agent regulations in that, specifically, 42 USC 262 had appointed a Responsible Official and had developed and implemented an incident response plan. The draft summary of findings further indicated that 42 USC 262 did not always: 1) ensure the physical security of select agents or restrict access to select agents to approved individuals; 2) ensure that individuals received select agent training; 3) maintain required inventory records or ensure that select agent inventory was stored only in registered areas; 4) or obtain DSAT approval to transfer select agents or ensure that only approved individuals accepted delivery of select agents. The summary of findings also stated that these weaknesses could have compromised 42 USC 26 ability to safeguard select agents from unintentional or intentional loss and to ensure the safety of individuals who work with select agents.

General and specific technical comments are attached to the CDC (b)(3) 42 USC 262a(h) response to the OIG, "Review of the Centers for Disease Control and Prevention's (b)(3) 42 USC 262a(h) (b)(3) 42 USC 262a(h) ComplianceWith Select Agent Regulations" (A-04-08-01056) dated June 23, 2010. While the CDC generally concurs in principle with findings in the report, there are several areas we would like to clarify and reiterate that policies and procedures are already in place after we self reported many of the finding indicated in the OIG report. The additional clarification is provided in the attached general and specific technical comments.

Thomas R. Frieden, M.D., M.P.H.
Director

Attachments: General Comments and Specific Technical Comments

Page 7 and Page 8, RECOMMENDATIONS

The first word in each bulleted item should appear in upper case type.